

REMARKS

This communication is responsive to the Office Action dated September 3, 2008. Reconsideration of the present application is respectfully requested in view of the foregoing amendments and the remarks which follow.

I. Restriction requirement

Applicants note with appreciation the rejoining of claim 14 with claims 1-8 and 13.

II. Information Disclosure Statement

Applicants note with appreciation the consideration of the previously submitted Information Disclosure Statement. A supplemental Information Disclosure Statement is provided herewith.

III. Objections to the specification

The Examiner objects to the abstract for failing to commence on a separate sheet (*see* Office Action at page 3). The original abstract appeared on the face page of the international application. A replacement abstract is submitted herewith, on a separate sheet. Thus, it is respectfully believed that the objection is overcome.

IV. Status of the claims

Claims 1, 3-7, 13 and 14 are amended, claims 2 and 8-12 are cancelled, and claims 15 and 16 are new.

Claims 9-12 are canceled without prejudice or disclaimer as being directed to a non-elected invention. Applicants reserve the right to pursue this subject matter in one or more divisional applications.

The amendments to claim 1 incorporate subject matter from claims 2 and 8 and are further supported, for example, in the specification at page 3, line 34 - page 5, line 10; page 5, lines 19-20; and page 6, lines 8-16. Claims 2 and 8 are cancelled in view of the amendments to claim 1. The broad and narrower limitations recited together in previous claim 4 are split into amended claim 4 and new claim 15. The broad and narrower limitations recited together in previous claim 5 are split into amended claim 5 and new claim 16. Claim 13 incorporates

subject matter from canceled claim 9, from which it depended. Additional clerical amendments are made to claims 1, 3-7, 13 and 14.

None of the foregoing amendments introduce new matter. The amendments are made solely to advance prosecution and not in acquiescence to any rejection. Further, they are made without prejudice or disclaimer of any canceled subject matter, and Applicants reserve the right to pursue any such subject matter in one or more continuing applications with the same rights of priority as the instant application.

Following entry of the amendments, claims 1, 3-7, and 13-16 will be pending.

V. The rejection under 35 U.S.C. § 112, second paragraph, is overcome

Claims 1-8, 13 and 14 are rejected as indefinite for reciting the phrase “in association with” and for reciting broad and narrower subject matter in the same claims. *See* Office Action at pages 3-5. The foregoing amendments are believed to fully address these issues. Thus, these rejections are believed to be overcome.

VI. The rejections under 35 U.S.C. § 102 are overcome

(a) “Applicants’ own admission”

At pages 5-6 of the Office Action, claims 1, 6 and 8 are rejected as allegedly anticipated by “Applicants’ own admission” regarding prior art Minirin® tablets marketed in a blister pack. Applicants respectfully traverse the rejection as applied to the pending claims.

The subject matter of claim 2, which was not rejected, has been incorporated into claim 1. Claim 6 depends from claim 1, and claim 8 is cancelled. Accordingly, it is believed that this rejection does not apply to the pending claims. Indeed, as taught in the specification, the cited prior art Minirin® tablet has a pH outside the range recited in the instant claims. *See* specification at page 4, lines 8-10. Thus, it cannot anticipate the instant claims, and so this rejection should be withdrawn.

(b) Flockhart

At page 6 of the Office Action, claims 1-5, 7, 8 and 13 are rejected as allegedly anticipated by U.S. 5,298,256 to Flockhart *et al.* ("Flockhart"). Applicants respectfully traverse the rejection as applied to the pending claims.

Flockhart does not describe a blister pack as claimed. For example, Flockhart does not disclose a blister pack containing a compressed tablet. Indeed, as noted at page 7 of the Office Action, Flockhart is directed to buccal patches. As such, the skilled artisan seeking to formulate and package a compressed tablet would not look to Flockhart for guidance. Thus, the §102 rejection based on Flockhart should be withdrawn.

VII. The rejection under 35 U.S.C. § 103 is overcome

At page 8 of the Office Action it is asserted that claims 1-8, 13 and 14 are obvious over Flockhart in view of WO 03/094886 to Nilsson *et al.* (hereinafter "Nilsson"). Applicants respectfully traverse.

The inability of Flockhart to teach or suggest the present invention is shown above. Nilsson cannot be relied upon to remedy the deficiencies of Flockhart, however, because Nilsson is not available as prior art against the instant claims.

The present application claims priority to November 13, 2003. Nilsson was published on November 20, 2003, from an application filed May 7, 2002, and claims priority to May 7, 2002. Therefore, Nilsson only could possibly qualify as prior art under 35 U.S.C. § 102(e). It does not, however, because of the applicability of §103(c):

(1) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

In the present case, the subject matter of Nilsson and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person, Ferring BV. For example, Ferring BV is the named Applicant on the cited PCT application and also is the assignee of the instant

application and its priority applications. Thus, the requirements of §103(c) are satisfied, and Nilsson does not qualify as prior art against the instant application. Thus, the rejection based on Nilsson should be withdrawn.

CONCLUSION

Applicants respectfully submit that all pending claims are in condition for allowance, and an early notice to this effect is earnestly solicited.

If there are any questions regarding the application, or if any issues remain, the Examiner is invited to contact the undersigned at the number below in order to advance prosecution.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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